DEC - 4 2000

K002761

Fresenius Medical Care

Fresenius Hemoflow F7NR^e, F50NR^e, and F70NR^e Hemodialyzers
510(k) Premarket Notification

Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990.

A. Submitter's Information:

Name:	Fresenius Medical Care North America
Address:	95 Hayden Ave Two Ledgemont Center Lexington, MA 02420
Phone:	1-781-402-9068
Fax:	(781) 402-9082
Contact Person:	Arthur Eilinsfeld, Director of Regulatory Affairs
Date of Preparation:	31 August, 2000

B. Device Name:

Common Name:

- F50NR^e and F70NR^e: Dialyzer, High Permeability with or without Sealed Dialysate System
- F7NR^e: Dialyzer, Capillary, Hollow Fiber

Product Code/Classification Panel:

- F50NR^e and F70NR^e: 78KDI/Gastroenterology-Urology
- F7NR^e: 78FJI/Gastroenterology-Urology

Classification:

- F50NR^e and F70NR^e: Class II per §876.5860
- F7NR^e: Class II per §876.5820

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C. Predicate Device Name:

The predicate devices for the Fresenius Hemoflow F7NR^e, F50NR^e, and F70NR^e Hemodialyzers are the Fresenius Hemoflow F7NR, F50NR and F70NR dialyzers cleared under the following premarket notifications:

- F7NR - #K874872 (2/19/88);
- F50NR - #K864169 (11/6/86);
- F70NR - #K864169 (11/6/86);
- F7NR, F50NR and F70NR - #K926005 (8/23/94).

D. Device Description/Indications for Use:

F7NR^e, F50NR^e, and F70NR^e Hemoflow dialyzers are designed for single use acute and chronic hemodialysis.

E. Substantial Equivalence:

1. Is the product a device?

YES - The F7NR^e, F50NR^e, and F70NR^e are devices pursuant to 21 CFR §201 [321] (h).

2. Does the new device have the same intended use?

YES – The intended use for the F7NR^e, F50NR^e, and F70NR^e is identical to that for the Fresenius F7NR, F50NR and F70NR and is as follows:

Intended Use for F7NR^e, F50NR^e, and F70NR^e

F7NR^e, F50NR^e, and F70NR^e Hemoflow dialyzers are designed for single use acute and chronic hemodialysis.

Intended Use for F7NR, F50NR, and F70NR

F7NR, F50NR, and F70NR Hemoflow dialyzers are designed for single use acute and chronic hemodialysis.

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3. **Does the device have technological characteristics that raise new types of safety or effectiveness questions?**

   NO – The F7NR^e, F50NR^e, and F70NR^e are equivalent to the currently manufactured F7NR, F50NR and F70NR, respectively. The current F7NR, F50NR and F70NR dialyzers are sterilized by ethylene oxide, the F7NR^e, F50NR^e, and F70NR^e will be sterilized by e-beam radiation. The technological characteristics of the F7NR^e, F50NR^e, and F70NR^e are equivalent to those of the F7NR, F50NR and F70NR and raise no new types of safety or effectiveness questions.

4. **Does descriptive or performance information demonstrate equivalence?**

   YES – Fresenius Medical Care North America believes that the information provided in this submission clearly describes the F7NR^e, F50NR^e, and F70NR^e and demonstrates that they are substantially equivalent to the F7NR, F50NR, and F70NR, respectively.

F. Safety Summary

The Fresenius F7NR^e, F50NR^e, and F70NR^e hemodialyzers are substantially equivalent in construction, design, materials, and intended use to the commercially available Fresenius F7NR, F50NR and F70NR hemodialyzers. In addition, testing of the F7NR^e, F50NR^e, and F70NR^e hemodialyzers indicate that the dialyzers are safe and effective for their intended use.

G. General Safety and Effectiveness Concerns

The device labeling contains a Package Insert, which includes indications for use, cautions and warnings, as well as the general operating instructions required for proper use of the device. This information promotes safe and effective use of the dialyzer.

Arthur Eilinsfeld
Director of Regulatory Affairs

8/31/00
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 4 2000

Mr. Arthur Eilinsfeld
Director of Regulatory Affairs
Fresenius Medical Care – North America
Two Ledgemont Center
95 Hayden Avenue
LEXINGTON MA 02420-9192

Re: K002761
Fresenius Hemoflow F7NR^e, F50NR^e,
and F70NR^e Hemodialyzers
Dated: August 31, 2000
Received: September 5, 2000
Regulatory Class: II
21 CFR §876.5820/Procode: 78 FJI
21 CFR §876.5860/Procode: 78 KDI

Dear Mr. Eilinsfeld:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Fresenius Medical Care

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Indications for Use Statement

Device Name:

Fresenius Hemoflow F7NR^e, F50NR^e, and F70NR^e Hemodialyzers

Indications for Use:

F7NR^e, F50NR^e, and F70NR^e Hemoflow dialyzers are designed for single use acute and chronic hemodialysis.

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

David A. Feigal

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002761